TABLE 49-continued

Determination of Respirable Dose, 1 mg/mL Fentanyl							
Determination of respirable dose in fentanyl sublingual spray by cascade impaction						Report Results	
CI Run	Sample	Fentanyl (µg/ dose)	Particle Size groupings	Groupings percent	Average Shot weight (mg)	Total Mass <9 µm (µg)	Respirable dose <9 µm (µg)
1	Globe	76.5694	≥9 µm	96.4	85.4	2.9	3.6
	Plate 0	0.5479					
	Plate 1	0.6228	9 µm > X ≥ 5.8 µm	0.8			
	Plate 2	0.4746	<5.8 µm	2.9			
	Filter	1.8149					
2	Globe	78.6941	≥9 µm	96.6	84.0	2.8	3.4
	Plate 0	0.6746					
	Plate 1	0.6217	9 µm > X ≥ 5.8 µm	0.8			
	Plate 2	0.5000	<5.8 µm	2.6			
	Filter	1.6740					
3	Globe	78.0529	≥9 µm	97.1	85.3	2.3	2.9
	Plate 0	0.5082					
	Plate 1	0.5429	9 µm > X ≥ 5.8 µm	0.7			
	Plate 2	0.4185	<5.8 µm	2.2			
	Filter	1.3596					
		Average percent respirable dose					3.3

Many other variations of the present invention will be apparent to those skilled in the art and are meant to be within the scope of the claims appended hereto, including but not limited to the particular unit dose or bi-dose devices and the particle size range of fentanyl produced, as well as other numerical parameters described in the examples, and any combination thereof.

What is claimed is:

1. A sublingual formulation comprising discrete liquid droplets of an effective amount of fentanyl or a fentanyl derivative selected from the group consisting of sufentanil, carfentanil, lofentanil and alfatenil, a free base or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable liquid carrier; said droplets having a mean diameter of from about 30 to about 70 microns.

2. A non-propellant sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl a free base, or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable liquid carrier, wherein the sublingual fentanyl formulation comprises:

from about 0.001% to about 15% by weight fentanyl free base;

from about 50% to about 60% by weight of ethanol; and

from about 4% to about 6% by weight of propylene glycol; said droplets having a mean diameter of at least about 10 microns.

3. A non-propellant sublingual fentanyl formulation comprising discrete liquid droplets of an effective amount of fentanyl a free base, or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable liquid carrier, wherein the sublingual fentanyl formulation consists essentially of:

from about 0.001% to about 15% by weight fentanyl free base;

from about 50% to about 60% by weight of ethanol; and

from about 1% to about 30% by weight of propylene glycol; said droplets having a mean diameter of at least about 10 microns.

4. A multi-dose device for sublingual administration of a drug comprising:

a reservoir containing the liquid formulation comprising fentanyl, or a fentanyl derivative selected from the group consisting of sufentanil, carfentanil, lofentanil and alfatenil, a free base or a pharmaceutically acceptable salt thereof, in a pharmaceutically acceptable liquid carrier; and

the device having an actuator which when actuated delivers a therapeutically effective dose of the liquid formulation in the form of liquid droplets having a mean diameter of from about 30 to about 70 microns.

5. A method of treating pain comprising sublingually administering an effective amount of the sublingual formulation according to claim **1** to a human patient experiencing pain.

* * * * *